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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/506,715

09/07/2004

Massimo Bresciani

451225-013

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04/30/2008

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EXAMINER

HELM, CARALYNNE E

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

04/30/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/506,715	Applicant(s) BRESCIANI ET AL.	
	Examiner CARALYNNE HELM	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 16-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/11/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Election/Restrictions***

Applicant's election with traverse of Group I in the reply filed on March 24, 2008 is acknowledged. The traversal is on the grounds that the identified common technical feature is not viewed by the applicant as that which constitutes the special technical feature that connects the inventions. This is not found persuasive for several reasons. According to MPEP 1850 section II, "Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims." The groups established by the restriction requirement are governed by claims 1, 16 and 20. Although claim 20 references to instant claim 16, it is not a dependent claim in the sense of PCT Rule 16.4 as it adds no additional features to the claimed limitations it references. The commonality of each of these claims is a recitation of the treatment of a cross-linked polymer with a supercritical fluid. Although applicant cites that their contribution over the prior art is the concept of drug loading via a supercritical fluid to a material previously treated with a supercritical fluid, this feature is only recited in claim 1. The possible future application of such a process to the material referred to in claim 16 has no bearing on the technical features currently recited in claim 16. Furthermore, claim 16 recites "enhanced drug loading properties" conferred to a cross-linked polymer after treatment with a supercritical fluid which, based upon applicant's disclosure, is a property linked to this known treatment process. In addition, the product of claim 20 neither recites nor refers to a claim that recites the limitation that it is the result of supercritical fluid loading of a drug into a cross-linked polymer. Instead its connection to claim 16, as well as claim 1, is through the technical feature of a cross-linked polymer treated with a supercritical fluid. Thus the technical feature that links each of the three groups is a cross-linked polymer treated

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with a supercritical fluid, which was known in the art at the time of invention and therefore cannot be deemed as a “special” technical feature.

The requirement is still deemed proper and is therefore made FINAL.

Claims 16-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 9 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant recites that the drug in the cross-linked polymer is “in high amorphous and nanocrystalline fraction”. The specification provides no description of what such a property actually means. Thus it is unclear what property of the material is actually being claimed (e.g. semi-crystalline structure, a combination of separate nanocrystalline structures and amorphous structures, etc.) nor what constitutes a “high” level of this property.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Allada (U.S. Patent No. 4,695,621 – see IDS).

Allada discloses the treatment of a cross-linked polystyrene polymer with a supercritical carbon dioxide for 1 to 2 hours (see column 6 lines 5-24, 38, and 41 and claims 1-2, instant claims 10-15). The treatment is taught to be performed under static conditions (see column 6 lines 5-24, 38, and 41; instant claim 13). Therefore claims 10-15 are unpatentable over Allada.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The four factual inquiries of *Graham v. John Deere Co.* have been fully considered and analyzed in the rejections that follow.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

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claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lai et al. (U.S. Patent No. 6,670,454) in view of Carli et al. (WO 99/25322- see IDS).

Lai et al. teach a method where a cross-linked biodegradable polymer is treated with a pure supercritical fluid (see abstract and claim 12; instant claim 1). Specifically, Lai et al. teach that the cross-linked polymers can be polysaccharides, as well as ordinary synthetic polymers (see column 3 lines 38-48; instant claim 8). In a particular embodiment, the cross-linked polymer is taught to be treated with pure supercritical carbon dioxide for 1 hour (see column 5 lines 18-21; instant claims 1-3 and 7). Although, Lai et al. teach that the supercritical fluid treated cross-linked polymers of their invention are useful as drug delivery systems, they do not teach the steps necessary to produce such a device (see column 4 lines 38-39).

Carli et al. teach a method of impregnating a cross-linked polymer with a drug (making a drug delivery system) using a supercritical fluid (see abstract; instant claim 1). Specifically, Carli et al. teach the steps where the drug is dissolved in the supercritical fluid, then the cross-linked polymer is contacted with this drug containing fluid impregnating the polymer with the drug, then the supercritical fluid is removed resulting in a drug loaded cross-linked polymer (see page 2 lines 6-10; instant claim 1). Carli et al. go on to teach that the contacting of the drug loaded supercritical fluid can occur via a static and/or dynamic process for 15 minutes to 24 hours (see page 2 lines 22-26 and line 31-page 3 line 3; instant claims 4-6). The particular supercritical

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fluids taught for use in the process of Carli et al. include carbon dioxide, ethylene, propylene, and nitrous oxide (see page 2 lines 15-19; instant claim 7). Further, Carli et al. teach a collection of cross-linked polymers suitable for their process which include cross-linked polyvinyl pyrrolidone, cross-linked sodium carboxymethyl cellulose (interpreted as cross-linked cellulose), cross-linked sodium starch glycolate (interpreted as cross-linked starch), cross-linked polystyrene, and cross-linked acrylic acid, all of which fall into the categories of those taught by Lai et al. (see page 3 lines 17-22; instant claim 8). The technique of drug impregnation with a supercritical fluid was recognized as part of the ordinary capabilities of one skilled in the art. As a result, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the method of Carli et al. with that of Lai et al., where the specific polymers taught by Carli et al. are used in the invention of Lai et al. Lai et al. in view of Carli et al. do not specifically teach that the drug precipitates inside the cross-linked polymer nor the nature (nanocrystalline, amorphous character) of the drug. However, applicant's disclosure on page 2 of the specification states that the method of Carli et al. was employed by the applicant and the desired characteristics (nanocrystalline and amorphous character) of the drug within the cross-linked polymer was attained (see instant specification page 2 lines 7-9 and 15-17). Further, since the method of impregnating the polymer with the drug taught by Carli et al. is the same as that claimed, the resulting structure would have the same properties as those claimed present in the result of the claimed method. Thus the teachings of Lai et al. in view of Carli et al. meet the limitations of impregnated drug recited in instant claims 1 and 9. Therefore claims 1-9 are obvious over Lai et al. in view of Carli et al.

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Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARALYNNE HELM whose telephone number is (571)270-3506. The examiner can normally be reached on Monday through Thursday 8-5 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615

/Caralynne Helm/
Examiner, Art Unit 1615